

Message Text

UNCLASSIFIED

PAGE 01 STATE 009069

15

ORIGIN HEW-06

INFO OCT-01 EA-10 ISO-00 OES-05 NEA-09 ARA-10 EUR-12 RSC-01

/054 R

66617

DRAFTED BY: DHEW/FDA/JRWEINROTH

APPROVED BY: OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

NEA/RA:TGRANT INFO

ARA/NSC-IG:RJBLOOMFIELD INFO

EA/RA:CCHAPMAN INFO

EA/ROC:KWEAVER INFO

EUR/NSC-IG:JROUSE INFO

----- 029554

R 142257Z JAN 75

FM SECSTATE WASHDC

TO AMCONSUL HONG KONG

UNCLAS STATE 009069

E.O. 11652: N/A

TAGS: ETRD, TBIO, XX

SUBJECT: RECALL OF MEDICAL DEVICE - BENNETT MONITORING
SPIROMETER AND ALARM

REFERENCE: HONG KONG 0195; STATE 1981

1. FDA ADVISES THAT NO REPEAT NO PHYSICAL RECALL OF DEVICES
HAS YET OCCURRED.

2. RECOMMEND INFORMING CONSIGNEE THAT LETTER FROM FIRM TO
DISTRIBUTORS ADVISES THAT USERS OF DEVICES SHOULD ENSURE
INTEGRITY OF BOTH EXPIRATORY DIAPHRAGM VALVE AND ITS CONNECTING
RUBING WHEN CONNECTED TO ANY PRESSURE OR VOLUME VENTILATOR
PRIOR TO AND DURING USE OF SUCH APPARATUS. CONSIGNNESS MAY OR
MAY NOT HAVE BEEN RECIPIENT OF WARNING LETTER. KISSINGER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 14 JAN 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE009069
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA/JRWEINROTH
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750015-0069
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750152/aaaabtve.tel
Line Count: 51
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 1
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 75 HONG KONG 0195, 75 STATE 1981
Review Action: RELEASED, APPROVED
Review Authority: ShawDG
Review Comment: n/a
Review Content Flags:
Review Date: 15 APR 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <15 APR 2003 by McShalBA>; APPROVED <17 FEB 2004 by ShawDG>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
05 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: RECALL OF MEDICAL DEVICE - BENNETT MONITORING SPIROMETER AND ALARM
TAGS: ETRD, TBIO, XX, US, BENNETT RESPIRATION PRODUCTS INC
To: HONG KONG
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006